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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,209	12/22/1999	MIHAIL N. KARPUSAS	B189	6529

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/180,209

Applicant(s)

KARPUSAS ET AL.

Examiner

Marjorie Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,39,41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12,39,41 and 42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>22</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

In view of the new grounds of rejection set forth below, the finality of the office action mailed 4/10/01 is hereby withdrawn. The amendment filed 8/15/01 has been entered and a nonfinal action on the merits of pending claims 12, 39, and 41-42 follows. In view of the cancellation of claims 38 and 40, all rejections of claims 38 and 40 are hereby withdrawn.

Specification

The abstract of the disclosure is objected to because it is more than one paragraph in length. Appropriate correction is required. See MPEP § 608.01(b).

Oath/Declaration

The new declaration filed 8/15/01 is acceptable.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 12, 39, and 41-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 12 and 41 are directed to a computer readable medium encoded with data comprising structure coordinates for amino acids in a CD40 ligand (CD40L). The structure coordinates are nonfunctional descriptive material as they do not impart any functionality to the computer readable medium nor do they display any functional

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relationship with a computing process. Merely storing nonfunctional descriptive material on a computer readable medium does not render the claimed invention statutory. See MPEP 2106.II.A, which states, "Apart from the utility requirement of 35 U.S.C. 101, usefulness under the patent eligibility standard requires significant functionality to be present to satisfy the useful result aspect of the practical application requirement. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make the invention eligible for patenting." In addition, MPEP 2106.IV.B (1) states that "When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re *Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)."

Nonfunctional descriptive material is defined by MPEP 2106.IV.B.1 (b) as: "Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either

as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).) The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture."

Claims 39 and 42 recite a machine comprising a computer readable medium similar to that of claims 12 and 41. Although a machine is an article of manufacture, it is noted that no structural/physical limitations are recited for the machine, therefore the machine is merely a "carrier" for the nonfunctional descriptive material, similar to the computer readable medium above. The structural coordinates recited in the claims do not impart functionality to the machine nor do they enter into any interfunctional relationship with the machine, therefore the structural coordinates do not provide a practical application for the machine claimed. See MPEP 2106.IV.B.2 (a), which states,

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"If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product. See, e.g., Lowry, 32 F.3d at 1583, 32 USPQ2d at 1034-35; Warmerdam, 33 F.3d at 1361-62, 31 USPQ2d at 1760.

Office personnel must treat each claim as a whole. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture."

Applicant's arguments filed 1/3/01 have been fully considered but they are not persuasive. In response to applicant's argument that the machine readable medium and structure coordinates are functionally interrelated because a three-dimensional representation can be displayed when the coordinates are read by a an appropriate machine, it is noted that the mere fact that the data/structural coordinates can be "read" by a machine does not impart functionality to either the coordinates themselves nor the medium in which they are stored. Applicant is reminded of the comparison to music set forth above. Music on a machine-readable medium (e.g. a CD-ROM) must "interrelate" with a machine in order to be displayed; however, the music itself does not have a functional relationship with either the medium nor the machine itself; it is merely "read" by the machine for display without any effect on the music itself, the medium or the machine. Similarly, the coordinates claimed do not, in themselves, functionally interact with the medium in which they are stored nor the machine in which they are displayed, and therefore do not impart functionality to the medium or machine. As the claims recite only nonfunctional descriptive material embodied on a computer readable medium or a

machine, but do not recite any other hardware limitation or functional relationship with the hardware, the claims are rejected as being directed to nonstatutory subject matter.

Claim Rejections - 35 USC § 112

In view of the amendment and arguments set forth in the response filed 10/15/01 and in view of the length of Table 1, the rejections set forth under 35 USC 112, second paragraph are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 39 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for while being enabling for a computer readable storage medium or machine comprising such a medium, wherein the medium comprises data capable of displaying a three-dimensional (3D) representation of a crystal of residues 116-261 of human cD40 ligand (CD40L), does not reasonably provide enablement for a machine or medium comprising data for displaying a crystal of any CD40L complex, non-human CD40 ligands, full-length CD40 ligands, mutants or variants of any CD40 ligand, or any CD40L fragment other than residues 116-261.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

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Applicant's arguments filed 10/15/01 have been fully considered but they are not persuasive. As previously set forth and in response to applicant's repeated argument that the specification discloses a method for crystallizing and obtaining structure coordinates for CD40 ligand proteins and provide an example thereof, it is noted that the specification exemplifies a method of crystallizing and obtaining structure coordinates for ONLY residues 116-261 of a human CD40 ligand (p. 33, Example C). In the response filed 10/15/01, applicant points to pages 33-40 of the instant specification for support that one skilled in the art would know how to obtain the crystal forms of CD40L or CD40L mutants. It is again noted that the instant specification teaches ONLY crystallization of sCD40L, which is defined on page 33 as residues 116-261. No examples or coordinates are disclosed for crystals of any complex of CD40L or fragment of CD40 ligand with any other molecule, nor for a full-length CD40L nor for a full-length or fragment of a non-human CD40L nor for any variant or mutant of a CD40L or fragment thereof. Applicant fails to provide any evidence anywhere that a crystallized CD40L, or any mutant or derivative thereof, other than sCD40L, was known at the time of invention. Although the specification states on page 7 that the disclosed crystal structure can "be used to solve" crystal structures of mutant or homologous CD40L molecules, or of fragments or co-complexes of CD40L, the specification does not specifically disclose how to do so. The applicants admit, on page 4 of the specification, that merely knowing a sequence of a compound does not allow an accurate prediction of the crystal structure of a protein or ligand. In addition, it is known in the art that a change in a single residue can be sufficient to significantly perturb a protein's structure

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and function (e.g. substituting a proline for a residue in a alpha helix may cause a "kink" such that the helix can no longer form). Any perturbation in the sequence or structure of any part of the protein would also be expected to perturb the crystal structure of the binding domain in the full-length protein, therefore knowing the crystal structure of an isolated binding domain does not necessarily predict the crystal structure of a full-length protein, of any other domain, or of the binding domain as part of a full-length protein which is a mutant or variant of CD40L. In addition, it is well known in the art that even small changes in crystallization conditions can cause differences in the crystal formed. For example, difference in salt conditions, temperature, etc. can cause the tertiary structure of a protein to change. As one purpose of crystallization is to "freeze" the tertiary structure, it is clear that differences in tertiary structure caused by different conditions will result in different crystal structures, even of the same protein. For these reasons, the examiner maintains that mere knowledge of the crystal structure of a "portion" (e.g. a domain or subunit) of a protein does not predicate knowledge of the crystal structure of the entire protein. Further, as changes in the structure or sequence of a protein may perturb its tertiary structure, knowledge of the crystal structure of a single portion (e.g. domain or subunit) of a protein does not predicate the crystal structure of a mutated or changed protein or portion thereof. The level of skill in the art is acknowledged to be high; however, given the degree of uncertainty in the art set forth above, the examiner maintains that it would require undue experimentation for one skilled in the art to make and/or use a computer readable medium or machine

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comprising crystal coordinates for any protein or portion thereof other than that consisting of amino acids 116-261 of CD40L.


Conclusion

Claims 12, 39, and 41-42 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.


Marjorie A. Moran
Examiner
Art Unit 1631

January 22, 2002


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